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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/657,061	09/05/2003	Jerome Legerton	30682-2	9098
7590		12/07/2004	EXAMINER	
Peter R. Martinez, Esq.		STULTZ, JESSICA T		
Suite 200		ART UNIT		
11988 El Camino Real		PAPER NUMBER		
San Diego, CA 92130		2873		

DATE MAILED: 12/07/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

10/657,061

Applicant(s)

LEGERTON ET AL.

Examiner

Jessica T Stultz

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 01 November 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-61 is/are pending in the application.
- 4a) Of the above claim(s) 12-43 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-11 and 44-61 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 05 September 2003 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)                        | 4) <input type="checkbox"/> Interview Summary (PTO-413)                     |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)               | Paper No(s)/Mail Date. _____  |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date <u>0903, 1203, 0904</u> .  | 6) <input type="checkbox"/> Other: _____                                    |

**DETAILED ACTION*****Election/Restrictions***

Applicant's election of Group Ia, claims 1-11 in the reply filed on November 1, 2004 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

***Double Patenting***

Claims 52-61 objected to under 37 CFR 1.75 as being a substantial duplicate of claims 1-10. When two claims in an application are duplicates or else are so close in content that they both cover the same thing, despite a slight difference in wording, it is proper after allowing one claim to object to the other as being a substantial duplicate of the allowed claim. See MPEP § 706.03(k). Specifically, the only difference between independent claims 52 and independent claim 1, is that the term DK is replaced by the definition of DK, gas permeability (Specification, page 7, lines 3-5). Therefore these terms have the exact same meaning, with a slight difference in wording and claim 52 is a duplicate of claim 1.

***Drawings***

New corrected drawings in compliance with 37 CFR 1.121(d) are required in this application because the drawings are informal and unclear. Applicant is advised to employ the services of a competent patent draftsman outside the Office, as the U.S. Patent and Trademark Office no longer prepares new drawings. The corrected drawings are required in reply to the Office action to avoid abandonment of the application. The requirement for corrected drawings will not be held in abeyance.

***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1, 11, and 52 (and therefore dependent claims 2-10, 44-51 and 53-61) are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Specifically regarding claims 1 and 11, the phrase “having a DK value of at least 30” is not clear because there are no units of measure for the value of DK. For purposes of examination and based on prior art references which refer to gas permeability (DK), it is assumed that DK is measured in units of ( $\times 10^{-11}$ ).

Specifically regarding claim 52, the phrase “having a gas permeability value of at least 30” is not clear because there are no units of measure for the value of DK. For purposes of examination and based on prior art references which refer to gas permeability (DK), it is assumed that gas permeability is measured in unit of ( $\times 10^{-11}$ ).

Claims 2-10, 44-51 and 53-61 are rejected because they inherit the indefiniteness of the claims from which they depend.

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

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Claims 1-7, 9-11, 44-48, 50-58, and 60-61 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sohnges in view of Ingenito et al.

Regarding claims 1, 6-7, 52, and 57-58, Sohnges discloses a hybrid contact lens (Column 4, line 113-Column 5, line 20, wherein the contact lens shown has two parts, specifically a hard portion "4" and a flexible portion "3", Figures 1-2) comprising: a substantially rigid portion (Column 4, line 113-Column 5, line 20, wherein the contact lens shown has a hard, rigid portion "4", Figures 1-2); and a substantially flexible portion coupled to the substantially rigid portion at a junction (Column 4, line 113-Column 5, line 20, wherein the hard, rigid portion "4" is coupled to the flexible portion "3", Figures 1-2); wherein the junction comprises an angled surface (Shown in Figures 1-2), but does not specifically disclose that the rigid portion has a DK/gas permeability of at least 30, specifically between 30 and 250 and is made of methyl methacrylate. Ingenito et al discloses a rigid contact lens having a gas permeability of at least 30, specifically between 30 and 250 made of methyl-methacrylate (Column 14, lines 27-61, Column 16, lines 35-56, and Column 17, line 57- Column 18, line 42, wherein the contact lens is made of MMA, methyl methacrylate for rigidity and the oxygen permeability falls within the given range of 30-250, Table 1B and Figure 3) for the purpose of providing a lens with high oxygen permeability while maintaining rigidity in a lens to form a more comfortable lens for the user (Column 17, line 57-Column 18, line 12, wherein the lens is made to have high oxygen permeability and rigidity). Therefore it would have been obvious to one having ordinary skill in the art at the time the invention was made for the lens of Sohnges to further include the rigid portion having a DK/gas permeability of at least 30, specifically between 30 and 250, made of methyl methacrylate since Ingenito et al discloses a rigid contact lens having a gas permeability of at

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least 30, specifically between 30 and 250 made of methyl methacrylate for the purpose of providing a lens with high oxygen permeability while maintaining rigidity in a lens to form a more comfortable lens for the user.

Regarding claims 11 and 47-48, Sohnges discloses a hybrid contact lens (Column 4, line 113-Column 5, line 20, wherein the contact lens shown has two parts, specifically a hard portion "4" and a flexible portion "3", Figures 1-2), comprising: a substantially rigid portion (Column 4, line 113-Column 5, line 20, wherein the contact lens shown has a hard, rigid portion "4", Figures 1-2); and a substantially flexible portion coupled to the substantially rigid portion at a junction (Column 4, line 113-Column 5, line 20, wherein the hard, rigid portion "4" is coupled to the flexible portion "3", Figures 1-2); wherein the junction comprises at least two intersecting planes (Shown in Figures 1-2), but does not specifically disclose that the rigid portion has a DK/gas permeability of at least 30, specifically between 30 and 250 and is made of methyl methacrylate. Ingenito et al discloses a rigid contact lens having a gas permeability of at least 30, specifically between 30 and 250 made of methyl-methacrylate (Column 14, lines 27-61, Column 16, lines 35-56, and Column 17, line 57- Column 18, line 42, wherein the contact lens is made of MMA, methyl methacrylate for rigidity and the oxygen permeability falls within the given range of 30-250, Table 1B and Figure 3) for the purpose of providing a lens with high oxygen permeability while maintaining rigidity in a lens to form a more comfortable lens for the user (Column 17, line 57-Column 18, line 12, wherein the lens is made to have high oxygen permeability and rigidity). Therefore it would have been obvious to one having ordinary skill in the art at the time the invention was made for the lens of Sohnges to further include the rigid portion having a DK/gas permeability of at least 30, specifically between 30 and 250, made of methyl

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methacrylate since Ingenito et al discloses a rigid contact lens having a gas permeability of at least 30, specifically between 30 and 250 made of methyl methacrylate for the purpose of providing a lens with high oxygen permeability while maintaining rigidity in a lens to form a more comfortable lens for the user.

Regarding claims 2, 44, and 53, Sohnges and Ingenito et al disclose and teach of a contact lens as shown above and Sohnges further disclose that the angled surface comprises a substantially V-shaped surface (Figure 2).

Regarding claims 3 and 54, Sohnges and Ingenito et al disclose and teach of a contact lens as shown above and Sohnges further disclose that the angled surface angled surface ranges between about 95 degrees to about 170 degrees (Figure 2).

Regarding claims 4, 45, and 55, Sohnges and Ingenito et al disclose and teach of a contact lens as shown above and Sohnges further disclose that the rigid portion has a diameter that ranges between 4.0 millimeters to about 12.0 millimeters (Column 3, lines 5-6, wherein the lens core has a diameter of 6-10 mm, which falls within the given range).

Regarding claims 5, 46, and 56, Sohnges and Ingenito et al disclose and teach of a contact lens as shown above and Sohnges further disclose that the substantially flexible portion has an outer diameter that ranges between about 10.0 millimeters to about 18.0 millimeters (Column 3, lines 5-6 and Column 3, line 120-Column 4, line 20, wherein the lens core is 10 mm and the edge part "3" or "9" is an additional 1 mm, therefore the outer diameter would be 11 mm, Figures 1-2).

Regarding claims 9, 50, and 60, Sohnges and Ingenito et al disclose and teach of a contact lens as shown above wherein the lens can be used to correct for various vision problems

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(Column 1, lines 13-22, Sohnges), but do not specifically disclose that the lens is constructed to include a prescription obtained from a wavefront aberrometer. However, examiner takes judicial notice that it is well known in the art of contact lenses for the lenses to have a prescription obtained from a wavefront aberrometer, for the purpose of determining an accurate prescription for the patient. Therefore it would have been obvious to one having ordinary skill in the art at the time the invention was made for the contact lens of lens of Sohnges and Ingenito et al to further include a prescription obtained from a wavefront aberrometer since it is well known in the art of contact lenses for the lenses to have a prescription obtained from a wavefront aberrometer, for the purpose of determining an accurate prescription for the patient.

Regarding claims 10, 51, and 61, Sohnges and Ingenito et al disclose and teach of a contact lens as shown above, but do not specifically disclose that the lens is constructed to include a prescription for presbyopia. However, examiner takes judicial notice that it is well known in the art of contact lenses for the lenses to include a prescription for presbyopia, for the purpose of helping the user accommodate to a change in focus of the user. Therefore it would have been obvious to one having ordinary skill in the art at the time the invention was made for the contact lens of Sohnges and Ingenito et al to further include a prescription for presbyopia since it is well known in the art of contact lenses for the lenses to include a prescription for presbyopia, for the purpose of helping the user accommodate to a change in focus of the user.

Claims 8, 49, and 59 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sohnges and Ingenito et al as applied to the above claims, and further in view of Graham.

Regarding claims 8, 49, and 59, Sohnges and Ingenito et al disclose and teach of a contact lens as shown above wherein the outer flexible portion is made from polyacrylate and



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hydroxyl groups (Column 5, lines 59-65, Sohnges), but do not specifically disclose that the flexible portion is made of a material from the claimed group. Graham teaches of a contact lens with a flexible outer periphery made of 2-hydroxyethyl methacrylate or poly HEMA (Column 1, lines 45-61 and Column 4, lines 58-63), for the purpose of providing diminished irritation to the eyelid and a comfortable insertion onto the ocular surface (Column 2, lines 34-43). Therefore it would have been obvious to one having ordinary skill in the art at the time the invention was made for the contact lens of lens of Sohnges and Ingenito et al to further include a flexible portion made of a material from the claimed group since Graham teaches of a contact lens with a flexible outer periphery made of 2-hydroxyethyl methacrylate or poly HEMA, for the purpose of providing diminished irritation to the eyelid and a comfortable insertion onto the ocular surface.

### ***Conclusion***

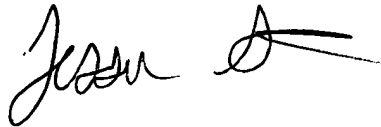
The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Novicky and Spinelli et al are cited as having some similar structure to the claimed invention.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jessica T Stultz whose telephone number is (571) 272-2339. The examiner can normally be reached on M-F 8-4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Georgia Epps can be reached on 571-272-2328. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



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November 30, 2004



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